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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,477	04/15/2004	Fabio Soldati	1/1490	8137

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,477	SOLDATI ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-200* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments and amended claims filed on 11/21/2007 is acknowledged.

Claims 1 and 10-11 have been amended. Claims 3-4 remain cancelled. Claims pending in the prosecution are claims **1-2 and 5-20.**

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2007 has been entered.

The following rejections of record are maintained.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 , 5-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of deVries et al. (US Patent No. 6,495,177 B1).

('777) discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (page 2, paragraph 6 and claim 2). DHA is disclosed on (page 4, paragraph, 4). ('777) further discloses that the composition can be in the form of pill, capsule, tablet, chewable candies form (page 6, paragraph, 6). ('777) does not teach the specific weight ratios of various components as claimed. However, with respect to the weight ratios of various components, it is the examiners position that optimization of such a parameter is within the purview of a skilled artisan by doing experimental manipulation absent evidence to the contrary. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

('777) does not teach problems associated with calcium in chewable multi vitamin tablet. deVries teaches an orally administrable nutritional supplement which is highly palatable, such as a chewable prenatal vitamin/mineral supplement. The supplement is preferably made in the form of a tablet that, upon chewing, dissolves rapidly in the mouth. The tablet is particularly suitable for administration of vitamins and minerals to women during pregnancy. The invention also includes methods of making and using such supplements (abstract). The invention comprises vitamins, carotene, iron, flavorants etc. Calcium is excluded from the solid dosage form or if present is in less than therapeutic amount DeVries further teaches that preferred absence of calcium from the tablet ensures minimal interference of iron absorption by minerals present in the tablet. (see column 7, lines 5-53 and column 11 ,lines 28-35).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to exclude calcium from the composition forwarded by ('777) because deVries teaches that absence of calcium from the tablet ensures minimal interference of iron absorption by minerals. A skilled artisan would thus have been motivated to formulate a composition comprising vitamins and minerals as claimed in the instant invention with an expectation of obtaining a dietary composition which would supplement the needs of a pregnant women with a reasonable success.

Response to Arguments

4. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

Applicants argue that the combination of the two references does result in the amended claim 1 since '777 reference discloses a composition comprising calcium in the form of pill, tablet or chewable candies and reference of de vries is also directed towards chewable supplement. Therefore the amended claims which are directed to non chewable composition are not obvious over the cited prior arts. In response to applicant's argument , the examiner respectfully cites that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The claims are given broadest reasonable interpretation during prosecution. Prior art teaches tablet in the composition. Applicants also claim formulation in the form of tablets in dependent claim 9. There is nothing in the prior art which teaches that the tablets cannot be chewed. Applicant is emphasizing the preferred embodiments of the references cited in the arguments, however, the prior art is evaluated for the full scope of what it reasonably suggests or what would have been obvious to the one of ordinary skilled in the art in light of the teachings of the prior art. In the instant case, '777 teaches a composition comprising the claimed components and de vries dissuades the use of calcium in the

composition. It would have been obvious to one of ordinary skilled in the art to formulate a composition without calcium and result in a claimed composition based on the teachings of both the references and by performing experimental manipulations with the amounts. It should be noted that being non chewable is property resulting from a specific combination of ingredients in a specific proportion, the independent claims as recited do not recite any specific amounts of the claimed components. Applicant has not provided any unexpected results in the form of scientific or technical data associated with the claimed components while the composition comprising the claimed components have been shown to be obvious to one of ordinary skilled in the art. The rejection is therefore maintained.

5. Claims 10-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387). The teachings of ('777) and devries have been discussed above. ('777) and de vries do not teach molybdenum, chromium and iodine in the composition.

Uiterwaal et al. teaches nutritional supplement preparation for pregnant and breast-feeding women based on milk constituents for pregnant and breast feeding women comprising iodine, calcium, phosphorus, various vitamins, chromium and molybdenum, niacin and folic acid etc. (see Table A in column 7, claim 5 and 8). Since the composition provides nutritional supplement to pregnant and breast feeding women, it would have been obvious to the one of ordinary skilled in the art at the time the

invention was made to incorporate nutrients such as iodine, chromium and molybdenum in the composition forwarded by ('777). A skilled artisan would have made a formulation comprising molybdenum, chromium, iodine, vitamins, minerals, niacin, folic acid and DHA with a reasonable expectation of success.

With respect to the weight ratios of various components and amounts, it is the examiners position that optimization of such parameters are within the purview of a skilled artisan by doing experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable range by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

6. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

Applicant mainly argues that the combination of references do not teach the claimed amendment of the tablet being in the non chewable form. This argument is not persuasive as the claims lack the specific amounts and proportions used in the composition, in the absence of which the claimed property of being non chewable would still be obvious. As discussed above there is nothing in the art that shows that the tablet cannot be chewed.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387) and DRUGDEVELOPMENT AND INDUSTRIAL PHARMACY, 12(8&9), 1133-1144 (1986) Robert F. Jimerson.

The teachings of ('777), devries and Uiterwaal et al. have been discussed above. The references do not teach oblong gelatin capsule. However, Robert F. Jimerson discloses soft gelatin capsule. Robert F. Jimerson further disclose that because of their special properties and advantages, soft gelatin capsules are employed for a wide variety of uses in pharmaceutical industries and are produced in a variety of shapes, sizes, and colors. Their current applications primarily include, oral dosage forms, suppositories and topical products (see page 1134, paragraph 2 and 3).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to make gelatin capsule of the oblong shape since the article teaches that gelatin capsules bear special properties and advantages in pharmaceutical compositions. A skilled artisan would have made gelatin capsule comprising various nutritional components comprising vitamins, minerals, folic acid, biotin and niacinamide with a reasonable expectation of success.

Response to Arguments

8. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

Applicant argues that the claim depends on claim 10 which recites the limitation of the dosage form being "non chewable" and thus the reference of Jimerson would not make it obvious to one skilled in the art to form the claimed non chewable tablet. This argument is not persuasive because Jimerson teaches that soft gelatin capsules are employed for a wide variety of uses in pharmaceutical industries as stated in the rejection above. Furthermore as stated above, claim 10 does not recite the specific amounts and proportions of various components, in the absence of such the invention as whole would have been obvious to one of ordinary skilled in the art at the time of invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall
Art Unit 1612

/S Kishore/

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